

Serial Number 10/694,033  
Art Unit 3627  
Atty. Docket No.: 4425-PA1C2

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Appellants:  
DAVID E. BERG, ET AL.

Serial No.:  
10/694,033

Atty. Docket No.:  
4425-PA1C2

Filed:  
25 October 2001

For:  
METHOD FOR DETECTING,  
TREATING, AND MONITORING  
CONDITIONS ASSOCIATED WITH  
ACTIVATION OF THE COAGULATION  
RESPONSE

Examiner: FORD, ALLISON M.

Art Unit: 1651

**REPLY BRIEF**

Mail Stop Appeal Brief-Patents  
Commissioner for Patents  
P.O. Box 1450  
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SIR:

This is a Reply Brief filed in response to the Examiner's  
Answer mailed 10 January 2008.

**I. STATUS OF THE CLAIMS**

1. Claims 1-69 are canceled. Claims 70-87 are new.  
Claims 70, 71, 72, 77, 78, and 84-87 were amended in the response dated 9 February 2007. Claims 70, 77, 84, and 86 are independent claims. Claims 71-76 depend from independent claim 70. Claims 78-83 depend from independent claim 77. Claim 85 depends from independent claim 84. Claim 87 depends from independent claim 86. Claims 70-87 are pending in this case, and are the claims subject to this appeal.
2. A copy of claims 70-87, the claims on appeal, is provided in Claims Appendix A accompanying the Appeal Brief.
3. Claims 70-72, 74-79, and 81-87 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Wintrobe et al.
4. Claims 70-87 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Sorensen et al.

5. Claims 70-87 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Dati et al.
6. Claims 77-83 are deemed substantial duplicates of claims 70-76.
7. Claim 84 is deemed a substantial duplicate of claims 74 and 81.
8. Claim 86 is deemed a substantial duplicate of claims 76 and 83.
9. Claims 70-87 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 45-63 of copending Application No. 10/915,018.

**II. GROUND OF REJECTION TO BE REVIEWED ON APPEAL**

1. Claims 70-72, 74-79, and 81-87 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Wintrobe et al. The first issue to be resolved in this appeal is, therefore, whether claims 70-72, 74-79, and 81-87 are patentable over Wintrobe et al.

2. Claims 70-87 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Sorensen et al. The second issue to be resolved in this appeal is, therefore, whether claims 70-87 are patentable over Sorensen et al.

3. Claims 77-83 are deemed substantial duplicates of claims 70-76. The third issue to be resolved in this appeal is, therefore, whether claims 77-83 are substantial duplicates of claims 70-76.

4. Claim 84 is deemed a substantial duplicate of claims 74 and 81. The fourth issue to be resolved in this appeal is, therefore, whether claim 84 is a substantial duplicate of claims 74 and 81.

5. Claim 86 is deemed a substantial duplicate of claims 76 and 83. The fifth issue to be resolved in this appeal is, therefore, whether claim 86 is a substantial duplicate of claims 76 and 83.

6. Claims 70-87 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 45-63 of copending Application No. 10/915,018. The sixth issue to be resolved in this appeal is, therefore, whether claims 70-87 unpatentable over claims 45-63 of copending Application No. 10/915,018.

### **III. ARGUMENT**

#### **A.**

**Issue:** Whether claims 70-72, 74-79, and 81-87 are patentable over Wintrobe et al.

Claims 70-72, 74-79, and 81-87 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Wintrobe et al. Appellants respectfully traverse this rejection. The claims are presented in one group by the examiner, that group of claims now on appeal being claims 70-72, 74-79, and 81-87. None of the claims necessarily stands or falls together.

#### Independent claims 70, 77, 84, 86

Wintrobe et al. disclose laboratory methods for the study of hemostasis, e.g., the stoppage of bleeding, and blood coagulation and blood clotting defects. Beginning on page 1049, Wintrobe et al. discusses tests to evaluate the process of hemostasis and blood coagulation in conjunction with Table 33-2, which represents commonly used tests to evaluate hemostasis and blood coagulation in normal subjects. Table 33-2 in Wintrobe et al. identifies tests to evaluate the process of hemostasis, e.g., the stoppage of bleeding, and blood coagulation, and the

normal range of those tests each relating to a specific blood coagulation factor. In Table 33-2 common causes of abnormalities in the factors of hemostasis and blood coagulation are listed. The process of hemostasis and blood coagulation is studied in Wintrobe et al. in a small superficial wound causing activation of the coagulation response in blood, in which the tests in Table 33-2 relate to the study of the hemostasis and blood coagulation process once activated and the normal ranges of blood coagulation factors.

On page 1053, Wintrobe et al. discuss platelet functions and platelet adhesiveness. On page 1060, Wintrobe et al. discuss methods for the quantitative assay of plasma fibrinogen as an example of a test of the coagulation phase. On pages 1060-1061, Wintrobe et al. discuss tests for intravascular coagulation and fibrinolysis, e.g., the enzymatic breakdown of fibrin. On page 1062, Wintrobe et al. discuss Table 33-3, which identifies four tests, e.g., platelet count, bleeding time, partial thromboplastin time, and prothrombin time, which may be used to diagnose blood clotting defects in bleeding patients.

***Wintrobe et al. evaluate blood coagulation factors. The tests in Tables 33-2 and 33-3 are tests carried out to evaluate***

***blood coagulation factors, not to identify low level activation of the coagulation response in blood.*** The evaluation of blood coagulation factors does is not the same performing different blood tests, each for identifying low level activation of the coagulation response in blood, on a blood sample and if at least two of the different blood tests identify low level activation of the coagulation response in the blood sample are abnormal then using the at least two of the blood tests to assist in diagnosing the subject with one of the conditions. This is where Wintrobe et al. and Appellants' claimed invention depart. Appellants' claims are not concerned with evaluating the dynamics of blood coagulation factors after the coagulation response is activated by forming a superficial wound as in Wintrobe et al. Wintrobe et al. clearly specifies activating the coagulation response in blood by forming a superficial wound and then examining the hemostasis process, namely, blood coagulation factors.

Appellants' claims are concerned with neither the levels of clotting factors in blood, nor with how or why clotting factors effect blood coagulation. Appellants' claims relate to identifying condition(s) that cause(s) low level activation of coagulation, providing different blood tests that are each for



identifying low level activation of the coagulation response in blood, performing each of the different blood tests on the blood sample, and if at least two of the different blood tests identify low level activation of the coagulation response in the blood sample are abnormal, using the at least two of the blood tests to assist in diagnosing the subject with one of the conditions, all of which is not specified in Wintrobe et al. Certain tests specified in Appellants' dependent claims overlap some of the tests in Wintrobe et al., but the present claims are method claims and the methods carried out in Wintrobe et al. are for a very different purpose which lead to very different outcomes or results as compared to the method specified in Appellants' claims. Accordingly, Wintrobe et al. do not, and cannot, anticipate Appellants' method claim 70, 77, 84, 86.

Dependent claims 71, 72, and 74-76

Claims 71, 72, and 74-76 depend upon claim 70 that is allowable according to the argument set forth above and, therefore, are allowable.

Dependent claims 78, 79, and 81-83

Claims 78, 79, and 81-83 depend upon claim 77 that is allowable according to the argument set forth above and, therefore, are allowable.

Dependent claim 85

Claim 85 depends upon claim 84 that is allowable according to the argument set forth above and, therefore, is allowable.

Dependent claim 87

Claim 87 depends upon claim 86 that is allowable according to the argument set forth above and, therefore, is allowable.

**B.**

**Issue:** Whether claims 70-87 are patentable over Sorensen et al.

Claims 70-87 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Sorensen et al. Appellants respectfully traverse this rejection. The claims are presented in one group by the examiner, that group of claims now on appeal being claims 70-87. None of the claims necessarily stands or falls together.

Independent claims 70, 77, 84, 86

The study in Sorensen et al. is to detect activation of coagulation and fibrinolysis in patients with fractures in the lower extremities. The study in Sorensen et al. proves substantial activation of coagulation as an immediate response to trauma.

***Appellants' claims are not concerned with determining whether activation of coagulation occurs in patients with fractures in the lower extremities.*** Clearly, substantial activation of the coagulation response does occur in patients suffering from fractures. Appellants' claims are not concerned with evaluating whether activation of coagulation is attributed to trauma. Rather, Appellants' claims relate to identifying condition(s) that cause(s) low level activation of coagulation, providing different blood tests that are each for identifying low level activation of the coagulation response in blood, performing each of the different blood tests on the blood sample, and if at least two of the different blood tests identify low level activation of the coagulation response in the blood sample are abnormal, using the at least two of the blood tests to assist in diagnosing the subject with one of the conditions, all of which is not specified in Sorensen et al.

Fractures in the lower extremities do not cause low level activation of the coagulation response in blood. To the contrary, according to Sorensen et al. fractures in the lower extremities cause substantial activation of coagulation. Accordingly, Sorensen et al. do not, and cannot, anticipate Appellants' claim 70, 77, 84, 86.

Dependent claims 71-76

Claims 71-76 depend upon claim 70 that is allowable according to the argument set forth above and, therefore, are allowable.

Dependent claims 78-83

Claims 78-83 depend upon claim 77 that is allowable according to the argument set forth above and, therefore, are allowable.

Dependent claim 85

Claim 85 depends upon claim 84 that is allowable according to the argument set forth above and, therefore, is allowable.

Dependent claim 87

Claim 87 depends upon claim 86 that is allowable according to the argument set forth above and, therefore, is allowable.

The claims on appeal are clear and unambiguous and are directed to the invention. Appellants' discussion of the patentability of claims subject to this appeal over Wintrobe et al. and Sorensen et al. is also clear and unambiguous. As explained above and in Appellants' Appeal Brief, Wintrobe et al. and Sorensen et al. each have no application toward the claims subject to this appeal. Although it has been repeatedly stated by the examiner that it is unclear what limitation of the claimed invention Appellants feel Wintrobe et al. and Sorensen et al. do not teach, Appellants have fully responded to the rejections of the claims according to the argument set forth above and the Appeal Brief and in prior responses in this case and have clearly identified the combination of claim limitations Wintrobe et al. and Sorensen et al. fail to show. Appellants' again respectfully submit that the content of Wintrobe et al. and Sorensen et al. each altogether fail to incorporate the subject matter claimed by Appellants in claims 70, 77, 84, 86, and the corresponding dependent claims, and that, therefore, Wintrobe et

al. and Sorensen et al. are each not properly applied to the claims on appeal. Claims 70, 77, 84, and 86 are each appropriate in scope, directed to the invention, and clear and unambiguous, as is each of the corresponding dependent claims.

This Reply Brief is responsive to the Examiner's Answer mailed 10 January 2008. All arguments made in Appellant's Appeal Brief filed 16 October 2007 are maintained.

Date: 9 March 2008

Respectfully submitted,

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